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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,017	03/23/2004	David Feygin	115-001US	4800
22897	7590	12/30/2008		
DEMONT & BREYER, LLC 100 COMMONS WAY, Ste. 250 HOLMDEL, NJ 07733			EXAMINER MUSSELMAN, TIMOTHY A	
			ART UNIT	PAPER NUMBER
			3715	
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			12/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/807,017	Applicant(s) FEYGIN ET AL.	
	Examiner TIMOTHY MUSSELMAN	Art Unit 3715	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 39-41 and 47-51 is/are allowed.
- 6) ☒ Claim(s) 42-46, 52-57, 59-61 and 63-70 is/are rejected.
- 7) ☐ Claim(s) 58 and 62 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

In response to applicant's communication dated 7/30/2008, claims 1-34 have been cancelled, and new claims 39-70 have been added and are currently pending. Claims 35-38 have been cancelled previously.

Claim Rejections - 35 USC § 102

The following is a quotation of the relevant portion of 35 U.S.C. 102 that forms the basis for the rejections made in this section of the office action;

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.

Claims 61 and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Lade (US 2,704,897).

Regarding claim 61, Lade discloses a palpation module comprising a pseudo-vein situated against a foam rubber tissue simulating structure. See col. 1: 50-74. Lade discloses wherein the system is covered in a simulated skin in col. 2: 6-9. Note that the foam rubber backing would effectively oppose any downward force on the vein. Lade further discloses obscuring the vein to control the difficulty with which it can be felt. See col. 2: 67-77.

Regarding claim 63, Lade discloses wherein the simulated vein is rigid. See col. 1: 15-25.

Claim Rejections - 35 USC § 103

The following is a quotation of the relevant portion of 35 U.S.C. 103 that forms the basis for the rejections made in this section of the office action;

(a) A patent may not be obtained though the invention is not identically disclosed or

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described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Claims 42-46, 52-53, 57, 59-60, and 64-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lade (US 2,704,897) in combination with Hoballah (US 6,398,557).

Regarding claims 42-44, Lade discloses a palpation module comprising a pseudo-vein. See col. 1: 50-74. Lade discloses wherein the system is covered in a simulated skin in col. 2: 6-9. Note that the foam rubber backing would effectively oppose any downward force on the vein. Lade does not disclose wherein the force can be varied but is constant during application (claims 42 and 43), or wherein the force is magnetic (claim 44). However, Hoballah teaches of a medical training device that utilizes magnetic forces to control feedback to the user regarding the tension of simulated skin. This citation also describes wherein this force is adjustable, but is substantially constant during application. In view of this teaching and in view of the broadness of applicant's claim, it would have been obvious to one of ordinary skill in the art to use this broad concept of magnetic force to control feedback in other medical training systems also, because it would be the application of a known feedback technique to a similar structure (similar in that it is a simulated physiological structure manipulated in a medical simulation). See MPEP 2143(B).

Regarding claim 45, Hoballah discloses wherein the force is adjustable, which could include a force slightly greater than the gravitational force. This would have been obvious as described above with regard to claim 44.

Regarding claim 46, Lade does not teach of a variable magnetic force. However, this is disclosed by Hoballah in col. 7: 36-50. In this citation Hoballah also teaches of using varying electromagnets (coils) in conjunction with permanent magnets to generate the appropriate magnetic fields. It would have been obvious to incorporate this broad concept into the system of

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Lade for the reasons and motivations set forth above with regard to the magnetic limitations in claim 44.

Regarding claims 52-53, Lade discloses a palpation module comprising a pseudo-vein. See col. 1: 50-74. Lade discloses wherein the system is covered in a simulated skin in col. 2: 6-9. Note that the foam rubber backing would effectively oppose any downward force on the vein. Lade also discloses a first and second opening in the structure (i.e. the housing). See fig. 4 and not the 2 openings wherein the tubes protrude out the ends of the structure. Lade does not disclose wherein the simulated stiffness of the pseudo-vein is variable. However, Hoballah teaches of a medical training device that utilizes magnetic forces to control feedback to the user regarding the tension (i.e. stiffness) of simulated skin. This citation also describes wherein this force is adjustable. In view of this teaching and in view of the broadness of applicant's claim, it would have been obvious to one of ordinary skill in the art to use this broad concept of magnetic force to control feedback (including simulated stiffness) in other medical training systems also, because it would be the application of a known feedback technique to a similar structure (similar in that it is a simulated physiological structure manipulated in a medical simulation). See MPEP 2143(B).

Regarding claim 57 and 69-70, Lade discloses a palpation module comprising a pseudo-vein. See col. 1: 50-74. Lade discloses wherein the system is covered in a simulated skin in col. 2: 6-9. Note that the foam rubber backing would effectively oppose any downward force on the vein. Lade does not disclose wherein the simulated stiffness of the pseudo-vein is variable. However, Hoballah teaches of a medical training device that utilizes magnetic forces to control feedback to the user regarding the tension (i.e. stiffness) of simulated skin. This citation also describes wherein this force is adjustable. In view of this teaching and in view of the broadness of applicant's claim, it would have been obvious to one of ordinary skill in the art to use this broad concept of magnetic force to control feedback (including simulated stiffness) in other medical training systems also, because it would be the application of a known feedback technique to a

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similar structure (similar in that it is a simulated physiological structure manipulated in a medical simulation). See MPEP 2143(B).

Regarding claim 59, Lade discloses in col. 2: 68-75 wherein the vein is controllably obscured so that it can be felt or not felt as desirable.

Regarding claim 60, these limitations are rejected as described above with regard to claims 42-44.

Regarding claims 64-67, these limitations are rejected as described above with regard to claims 42-44.

Regarding claim 68, see the rejection of claim 46 above.

Claims 54-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lade (US 2,704,897) in combination with Hoballah (US 6,398,557) and also with Cunningham et al. (US 6,470,302).

Regarding claims 54 and 56, neither Lade nor Hoballah teach of a skin stretch module. However, this is known in the art of vascular palpation modules. Cunningham discloses a vascular palpation module wherein the skin is stretched and measured (via an electronics interface), and the stretching indicates an occlusion technique is performed (for the update of the computer display). See col. 11: 32-54. It would have been obvious to one of ordinary skill in the art to update the system of Lade with current skin simulation technology as taught by Cunningham, in order to improve the device by making it more realistic and also providing feedback for performance evaluation purposes.

Regarding claim 55, Lade discloses wherein a needle is interfaced to the system. See fig. 1.

Allowable Subject matter

Claims 39-41 are considered allowable because the prior art does not teach or suggest wherein if sufficient pressure is applied to a simulated target structure during a palpation technique, the target structure is no longer detectable.

Claims 47-51 are considered allowable because the prior art does not teach or suggest a palpation module that utilizes the specific structure comprising a simulated anatomical member disposed on a first plate, movable towards a second plate, and wherein a sensor is indicative of the distance between said plates.

Claims 58 and 62 contain allowable subject matter, but are objected to for depending from a rejected base claim. These claims would be allowable if rewritten to include the limitations of the base claim and any intervening claims. These claims are considered allowable because the prior art does not teach or suggest wherein if sufficient pressure is applied to a simulated target structure during a palpation technique, the target structure is no longer detectable.

Response to Arguments

Applicant's arguments dated 7/30/2008 have been fully considered. Applicant's arguments that Lade does not disclose wherein the pseudo vein can be controllably obscured to be felt or not felt as desired are not persuasive. Lade clearly discloses in col. 2: 52-80 wherein a user can place different amounts of cotton under the skin between the vein and the skin to obscure the vein for precisely the purpose of adjusting the visibility and palpability of the vein. This is exactly the limitation applicant has claimed. Applicant has not claimed the details from the specification argued, or any actual mechanism at all for carrying out the claimed feature, and thus Lade clearly anticipates this feature.

Further arguments are moot in view of the new grounds of rejection.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY MUSSELMAN whose telephone number is (571)272-1814. The examiner can normally be reached on Mon-Thu 6:00AM - 4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Xuan Thai can be reached on (571)272-7147. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/T. M./
Examiner of Art Unit 3715

/XUAN M. THAI/
Supervisory Patent Examiner, Art Unit 3715